

Amendments to the Drawings

The attached sheet of drawings includes changes to Figure 2. This sheet, which includes Figures 1 and 2, replaces the original sheet including Figures 1 and 2. In Figure 2, reference numerals 30, 32 and 34 have been added.

Attachment: Four Replacement Drawing Sheets

REMARKS

Applicants have received and carefully reviewed the Office Action of the Examiner mailed September 13, 2006. Currently, claims 1-22 remain pending. Claims 1-22 have been rejected. In this amendment, claims 14, 15, and 17 have been amended and claim 16 has been canceled. Favorable consideration of the following remarks is respectfully requested.

Specification

Applicants have amended the specification to correct a typographical error on page 2, line 16. The word “h as” has been replaced with “has”.

Drawings

The drawings were objected to under 37 CFR 1.83(a). Applicant has amended Figure 2 of the drawings to include the inner tubular member 18 having an inner layer 30, an outer layer 34, and a tie layer 32 between the inner layer 30 and the outer layer 34. Additionally, Applicant has amended the specification at page 9, line 13-page 10, line 8 to include reference numerals 30, 32, and 34. Applicant has included replacement drawings believed to be in compliance with 37 CFR 1.121(d).

Rejections under 35 U.S.C. § 112

Claim 14 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office Action states that claim 14 recites the limitation “reinforcing tube” in line 1, which there is insufficient antecedent basis for. In response to the rejection, claim 14 has been amended to recite “reinforcing sleeve”. As such, claim 14 is believed to have sufficient antecedent basis and Applicants request withdrawal of the rejection.

Rejections under 35 U.S.C. § 102

Claims 1-4, 6-11 and 14 were rejected under 35 U.S.C. §102(b) as being anticipated by Sagae (5,176,637). After careful review, Applicants respectfully disagree.

The Office Action states that Sagae discloses “a catheter comprising an inflatable balloon (3), a catheter shaft (2), an inflation lumen (6), a guidewire lumen (4), a guidewire receiving tube (9), a tubular member (1), an outer member (2), and a reinforcing sleeve (14). (See Figure 1).” The Office Action continues to say, “[t]he reinforcing sleeve is attached to the outer member at a tack point. (See Column 5, Line 60-68) The reinforcing sleeve extends proximally to and past the tack point.”

Turning to claim 1, which recites:

1. A catheter comprising:
an inflatable balloon having a proximal end, a distal end, and an inflation cavity therebetween;
a catheter shaft having the inflatable balloon affixed proximate a distal end thereof, the catheter shaft having an inflation lumen fluidly connected to the balloon inflation cavity and a guidewire lumen extending through the balloon cavity within a tubular member which is affixed to the inflatable balloon proximate the distal end; and
a reinforcing sleeve, having a proximal portion and a distal portion with a lumen extending therethrough, wherein the distal portion of the reinforcing sleeve extends into the inflation cavity with at least a portion of the tubular member slidably disposed through the lumen thereof and the proximal portion of the reinforcing sleeve is fixed relative to the catheter shaft and disposed in the catheter shaft inflation lumen.

After careful review, Sagae does not teach, “wherein the distal portion of the reinforcing sleeve extends into the inflation cavity with at least a portion of the tubular member slidably disposed through the lumen thereof”, as recited in claim 1. Additionally, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

The tubular member slidably disposed through the lumen of the reinforcing member appears to be a structure limitation of claim 1 that the tubular member is not secured or attached to the reinforcing member. One advantage of having the tubular member slidably disposed through the lumen of the reinforcing member and not secured to it is that the tubular member is able to move relative to the reinforcing member and the catheter shaft. This allows the balloon having a distal end secured to the tubular member and a proximal end secured to the catheter shaft to be able to longitudinally expand or contract if needed during actuation of the balloon.

Furthermore, after careful review, Sagae does not teach the at least a portion of the tubular member (1) is slidably disposed through the lumen of the reinforcing member (14). In fact, it appears that the reinforcing member (14) of Sagae is firmly fixed between the inner tube (1) and the tapered portion of the outer tube (2). (Column 6, lines 11-15.) As such, it appears that the reinforcing member (14) is fixed relative to both the inner tube (1) and the outer (2). Thus, the inner tube (1) is not slidably disposed through the lumen of the reinforcing member (14), as recited in claim 1. Therefore, for reasons given above, as well as others, claim 1 is believed to be allowable over Sagae, and Applicants respectfully request withdrawal of the rejection.

Additionally, for similar reasons given above, as well as others, claims 2-4 and 6-10, which depend from claim 1 and include significant additional limitations, are believed to be allowable over Sagae and Applicants respectfully request withdrawal of the rejection.

Turning to claim 11, which recites:

- 11. A catheter comprising:
 - a guidewire tube having a distal end, a proximal end, a lumen therebetween, and an outer surface;
 - an outer tube disposed over the guidewire tube, the outer tube having a distal end, a proximal end and a lumen therebetween;
 - a balloon having a distal waist sealingly fixed to the guidewire tube, a proximal waist sealingly fixed to the outer tube, and an inflation cavity therebetween; and
 - a reinforcing sleeve having an outer surface attached to the outer tube, slidably disposed over the guidewire tube, and extending distally into the inflation cavity.

Claim 11 recites, “a reinforcing sleeve having an outer surface attached to the outer tube, *slidably disposed* over the guidewire tube, and extending distally into the inflation cavity.” As discussed previously, nowhere does Sagae teach or suggest the reinforcing sleeve slidably disposed over the guidewire tube. Therefore, for similar reasons given above, as well as others, claim 11 is believed to be allowable over Sagae, and Applicants respectfully request withdrawal of the rejection.

Additionally, for similar reasons given above, as well as others, claim 14, which depends from claim 11 and includes significant additional limitations, is believed to be allowable over Sagae, and Applicants respectfully request withdrawal of the rejection.

Claims 15-22 were rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al. (4,955,895). After careful review, Applicant respectfully disagree.

The Office Action states, "Sugiyama et al. discloses a catheter comprising a first elongate member (3), a second elongate member (1), a third elongate member (2), and an inflatable balloon member (10). (See Figure 2)." The Office Action further states, "the third elongate member comprises an elastic material such as ethylene-propylene. (See Column 6, Lines 36-44) The third elongate member is connected to the first elongate member by an adhesive material or by thermal fusion. (See Column 2 Lines 58-66)."

Turning to claim 15, which recites:

- 15. A catheter comprising:
 - a first elongate member having a proximal end, a distal end, and a lumen therebetween;
 - a second elongate member partially disposed in the lumen of the first elongate member having a proximal end, a distal end, and a lumen therebetween;
 - a third elongate member disposed on the second elongate member, the third elongate member having a distal end, a proximal end, and a lumen therebetween; and
 - an inflatable balloon member disposed on the second elongate member, the inflatable balloon member having a distal end, a proximal end, and a lumen therebetween;
 - wherein the distal end of the inflatable balloon member is sealingly connected to an outer surface of the second elongate member and wherein a proximal portion of the inflatable balloon member is sealingly connected to a first distal portion of the first elongate member;
 - wherein the third elongate member extends from a point proximal the distal end of the first elongate member to a point proximal the proximal end of the balloon;
 - wherein a portion of the third elongate member proximate the balloon is rigidly connected to a distal portion of the first elongate member; and
 - wherein the third elongate member is slidably disposed on the second elongate member.

After careful review, nowhere do Sugiyama et al. teach or suggest "wherein the third elongate member is slidably disposed on the second elongate member", as recited in amended claim 15. Claim 15 was amended to include the limitations of claim original claim 16.

In the Office Action, Figure 2 was cited as teaching the elements of claims 15-22. The corresponding description of Figure 2 of Sugiyama et al. recites in part:

In the present embodiment, for example, the leading end portion of the triple-flow catheter tube 4 is so constructed that the leading end of the outer tube 3 is tapered

to a diameter equal to or slightly smaller than the outside diameter of the middle tube 2 and fitted into the middle tube 2 and fastened thereto with an adhesive agent or by thermal fusion, *the middle tube 2 which is extended farther from the leading end of the outer tube 3 is similarly tapered to a diameter equal to or slightly smaller than the outside diameter of the inner tube 1 and fitted into the inner tube and fastened thereto with an adhesive agent or by thermal fusion, and the outer tube 3 and the middle tube 2 are severally provided slightly on basal sides thereof from the fastened positions mentioned above with lateral holes 11, 12 at least one each as illustrated in FIG. 2.* (Column 5, lines 27-43, emphasis added.)

Accordingly, Sugiyama et al. teach the middle tube (2) fastened to the inner tube (1) and secured with an adhesive. In such a configuration, the third elongate member (middle tube 2) cannot be slidably disposed on the second elongate member (inner tube 1), as recited in claim 15. Therefore, for similar reasons given above, as well as others, claim 15 is believed to be allowable over Sugiyama et al., and Applicants respectfully request withdrawal of the rejection.

Turning to claim 17, which recites:

17. The catheter of claim 15, wherein the proximal end of the third elongate member is proximate the ~~distal~~proximal end of the balloon.

Claim 17 has been amended to correct a typographical error. Support for the amendment can be found in the Figures and the Specification as filed. As amended, claim 17 recites, "the proximal end of the third elongate member is proximate the proximal end of the balloon." Nowhere do Sugiyama et al. teach or suggest the proximal end of the third elongate member being proximate the proximal end of the balloon.

Sugiyama et al. teach a vasodilating catheter having three flow paths formed by the catheter tube to communicate with the balloon. It appears that, in order for Sugiyama et al. to have the three flow paths, A, B, and C, the inner tube, middle tube, and outer tube all extend to the proximal end of the catheter. (See also Figure 1.) As such, the middle tube does not have a proximal end proximate to the proximal end of the balloon, which is positioned at the distal end of the catheter. Therefore, Applicants believes that Sugiyama et al. do not teach or suggest, "the proximal end of the third elongate member is proximate the proximal end of the balloon", as recited in claim 17. Therefore, for similar reasons given above, as well as others, claim 17, which depends from claim 15, is believed to be allowable over Sugiyama et al., and Applicants respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. § 103

Claim 5 was rejected under 35 U.S.C. §103(a) as being unpatentable over Sagae. Applicants respectfully traverse this rejection. For similar reasons given above, as well as others, claim 5, which depends from claim 1 and includes significant additional limitations, is believed to be allowable over Sagae, and Applicants respectfully request withdrawal of the rejection.

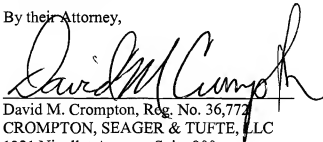
Claims 12 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sagae in view of Kastenhofer (6,659,977). Applicants respectfully traverse this rejection. For similar reasons given above, as well as others, claims 12 and 13, which depend from claim 11 and include significant additional limitations, are believed to be allowable over Sagae in view of Kastenhofer, and Applicants respectfully request withdrawal of the rejection.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,



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